

(19)



Europäisches Patentamt

European Patent Office

Office européen des brevets



(11)

EP 1 169 972 A1

(12)

EUROPEAN PATENT APPLICATION

(43) Date of publication:

09.01.2002 Bulletin 2002/02

(51) Int Cl.7: A61B 18/14

(21) Application number: 01305844.1

(22) Date of filing: 06.07.2001

(84) Designated Contracting States:

AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU
MC NL PT SE TR

Designated Extension States:

AL LT LV MK RO SI

(30) Priority: 07.07.2000 US 611617

(71) Applicant: Biosense Webster, Inc.
Diamond Bar, California 91765 (US)

(72) Inventors:

- Mest, Robert A.
Long Beach, California 90808 (US)
- Nakagawa, Hiroshi
Edmond Oklahoma 73003 (US)

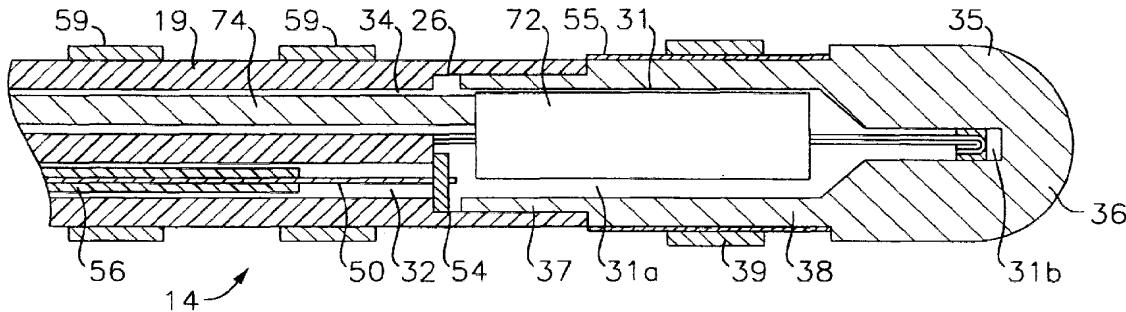
(74) Representative: Mercer, Christopher Paul et al
Carpmaels & Ransford 43, Bloomsbury Square
London WC1A 2RA (GB)

(54) Mapping and ablation catheter

(57) A catheter for mapping and ablating comprises an elongated flexible body having a distal region and at least one lumen extending therethrough. A tip electrode is mounted on the distal region. The tip electrode has an exposed distal region having proximal and distal ends and an isolated region proximal to the exposed distal region. The isolated region has an outer surface pro-

vided with an electrically insulating and thermally conductive layer. A second electrode is mounted on the isolated region of the tip electrode. This mapping and ablation electrode arrangement provides discrete recording of electrical signals due to the relatively small exposed distal region while allowing the creating of larger lesions due to the large thermal mass provided by the isolated region.

FIG. 3A



Description**FIELD OF THE INVENTION**

[0001] The present invention is directed to a catheter for electric diagnosis and treatment of the heart, and more particularly to a catheter for mapping and ablation.

BACKGROUND OF THE INVENTION

[0002] Electrode catheters have been in common use in medical practice for many years. They are used to stimulate and map electrical activity in the heart and to ablate sites of aberrant electrical activity.

[0003] In use, the electrode catheter is inserted into a major vein or artery, e.g., femoral artery, and then guided into the chamber of the heart which is of concern. Once the catheter is positioned within the heart, the location of aberrant electrical activity within the heart is then located.

[0004] One location technique involves an electrophysiological mapping procedure whereby the electrical signals emanating from the conductive endocardial tissues are systematically monitored and a map is created of those signals. By analyzing that map, the physician can identify the interfering electrical pathway. A conventional method for mapping the electrical signals from conductive heart tissue is to percutaneously introduce an electrophysiology catheter (electrode catheter) having mapping electrodes mounted on its distal extremity. The catheter is maneuvered to place these electrodes in contact with or in close proximity to the endocardium. By monitoring the electrical signals at the endocardium, aberrant conductive tissue sites responsible for the arrhythmia can be pinpointed.

[0005] For mapping, it is desirable to have a relatively small mapping electrode. It has been found that smaller electrodes record more accurate and discrete electrograms. Additionally, if a bipolar mapping arrangement is used, it is desirable that the two electrodes of the mapping arrangement be in close proximity to each other and that they be similar in size to produce more accurate and useful electrograms.

[0006] Once the origination point for the arrhythmia has been located in the tissue, the physician uses an ablation procedure to destroy the tissue causing the arrhythmia in an attempt to remove the electrical signal irregularities and restore normal heart beat or at least an improved heart beat. Successful ablation of the conductive tissue at the arrhythmia initiation site usually terminates the arrhythmia or at least moderates the heart rhythm to acceptable levels.

[0007] A typical ablation procedure involves providing a reference electrode, generally taped to the skin of the patient. RF (radio frequency) current is applied to the tip electrode, and current flows through the media that surrounds it, i.e., blood and tissue, toward the reference electrode. The distribution of current depends on the

amount of electrode surface in contact with the tissue as compared to blood, which has a higher conductivity than the tissue. Heating of the tissue occurs due to its electrical resistance. The tissue is heated sufficiently to

5 cause cellular destruction in the cardiac tissue resulting in formation of a lesion within the cardiac tissue which is electrically non-conductive. During this process, heating of the electrode also occurs as a result of conduction from the heated tissue to the electrode itself. If the electrode temperature becomes sufficiently high, a thin transparent coating of dehydrated blood protein can form on the surface of the electrode. If the temperature continues to rise, this dehydrated layer can become progressively thicker, resulting in char and/or thrombus on 10 the electrode surface. The creation of char and thrombus is unsafe, as the char and thrombus can be dislodged from the electrode during the procedure or during removal of the catheter after the procedure.

[0008] In clinical practice, it is desirable to reduce or 15 eliminate the formation of char and thrombus and, for certain cardiac arrhythmias, to create larger and/or deeper lesions. One method for accomplishing this end is to monitor the temperature of the ablation electrode and to control the RF current delivered to the ablation 20 electrode based on this temperature. If the temperature rises above a preselected value, the current is reduced until the temperature drops below this value.

[0009] Another method for determining whether char 25 and thrombus is forming is by monitoring the impedance. Specifically, because dehydrated biological material has a higher electrical resistance than endocardial tissue, impedance to the flow of electrical energy into the tissue also increases. A significant impedance rise thus indicates the formation of char and/or thrombus.

30 35 With a relatively large electrode, e.g., an 8 mm electrode, an impedance rise from char and thrombus formation may not be easily detected because the char and thrombus is formed over a relatively small percentage of the total surface area of the electrode. In contrast, if the electrically active surface area of the electrode is relatively small, char and thrombus will form over a relatively larger area of the electrode, making detection by impedance measurements easier.

[0010] The cooling effect of the blood on the electrode 40 45 is dependent on the thermal properties of the ablation electrode, and in particular its surface area. Typically ablation electrodes are relatively long, most commonly at least about 4 mm and up to about 8 mm, to provide sufficient surface area for cooling. However, such electrodes are less suitable for mapping because, as discussed above, more accurate electrograms can be obtained with a smaller mapping electrode. It is desirable for electrophysiologists use the same catheter for mapping and ablation during a single procedure because, 50 55 once a site is identified with a high resolution mapping electrode catheter as a target for therapy, it would be difficult to locate that site again with another catheter, particularly where the other catheter has a larger tip

electrode. Accordingly, a need exists for an electrode catheter that has a relatively small surface area for enhanced mapping, but has good thermal properties for enhanced cooling during ablation.

[0011] Another disadvantage of typical ablation electrodes is that it is sometimes difficult to accurately predict lesion size because the lesion size can vary depending on the orientation of the ablation electrode. For example, typically a 7 French catheter (having an outer diameter of just over 2 mm) is provided with an ablation tip electrode at its distal end having a length ranging from about 4 mm to about 8 mm. If the ablation electrode is provided in perpendicular relation to the tissue, a relatively small surface area of the electrode is in contact with the tissue. In contrast, a relatively larger surface area would be in contact with the tissue if the ablation electrode were in a generally parallel relationship to the tissue, i.e., if the ablation electrode were positioned on its side. It is often difficult for the physician to determine the precise orientation of the tip electrode relative to the tissue because the tissue is not visible with fluoroscopy. The size of the lesion is often related to the amount surface area in contact with the tissue. As a result, there is less predictability in lesion size.

[0012] Thus, although it is desirable to have a relatively long electrode for cooling purposes, it is desirable to have a relatively small electrically active surface area for obtaining more discrete electrograms, for more accurately detecting char and thrombus formation, and for enhancing the predictability of lesion size.

SUMMARY OF THE INVENTION

[0013] The invention is directed to an improved catheter for mapping and ablation. The catheter has an electrode arrangement at its distal end that provides more accurate mapping capability than a typical ablation electrode by having a relatively small surface area in contact with the tissue. Additionally, the electrode provides for better cooling than a typical mapping electrode by having an electrically insulating and thermally conductive region.

[0014] In one embodiment, the catheter comprises an elongated flexible body having a distal region and at least one lumen extending therethrough. A tip electrode is mounted on the distal region. The tip electrode has an exposed distal region having proximal and distal ends and an isolated region proximal to the exposed distal region. The isolated region has an outer surface provided with a electrically insulating and thermally conductive layer. A second electrode, preferably a ring electrode, is mounted on the isolated region of the tip electrode.

[0015] In another embodiment, the invention is directed to a catheter comprising an elongated flexible body having proximal and distal ends and at least one lumen extending therethrough. A tip section comprising a flexible tubing that is more flexible than the catheter body

is mounted at the distal end of the catheter body. The flexible tubing has proximal and distal ends and at least one lumen extending therethrough. A tip electrode is mounted on the distal end of the flexible tubing. The tip

5 electrode has an exposed distal region having proximal and distal ends and an isolated region proximal the distal region. The isolated region has an outer surface provided with an electrically insulating and thermally conductive layer. A ring electrode is mounted on the isolated region of the tip electrode.

[0016] The catheters of the present invention provide a tip electrode with an exposed region smaller than standard ablation electrodes. Yet the electrode provides enhanced cooling over standard mapping electrodes 15 due to the isolated region having an electrically insulating and thermally conductive coating. Additionally, the second or ring electrode, which is mounted directly on the tip electrode, can be closely-spaced to the exposed region of the tip electrode to allow close bipolar electrogram recording, thus providing more discrete electrograms.

[0017] In another embodiment, the invention is directed to a catheter comprising an elongated flexible body having a distal region and at least one lumen extending therethrough. A tip electrode is mounted on the distal region. The tip electrode has an exposed distal region having proximal and distal ends, a length and an outer diameter. The ratio of the length to the outer diameter ranges from about 0.8:1 to about 1.2:1. The tip electrode 25 also has an isolated region proximal the exposed distal region. The isolated region has an outer surface provided with an electrically insulating and thermally conductive layer. These uniform dimensions provide a generally constant contact area between the exposed region 30 of the tip electrode and the heart tissue, irrespective of the orientation of the tip section relative to the heart tissue. As a result, more predictable lesion sizes can be achieved.

40 DESCRIPTION OF THE DRAWINGS

[0018] These and other features and advantages of the present invention will be better understood by reference to the following detailed description when considered 45 in conjunction with the accompanying drawings wherein:

50 FIG. 1 is a side view of an embodiment of the catheter of the invention.

FIG. 2 is a side cross-sectional view of a catheter body according to the invention, including the junction between the catheter body and tip section.

FIG. 3A is a side cross-sectional view of a catheter tip section showing the lumens for the sensor cable and puller wire.

FIG. 3B is a side cross-sectional view of FIG. 3A showing the lumens for the sensor cable and thermocouple and electrode lead wires.

FIG. 3C is an enlarged view of the distal end of the thermocouple mounted in the tip electrode of the catheter of FIGs. 3A and 3B.

FIG. 4 is a longitudinal cross-sectional view of the tip section illustrated in FIGs. 3A and 3B.

FIG. 5 is a side view of an electrode arrangement in accordance with the invention.

DETAILED DESCRIPTION

[0019] In a particularly preferred embodiment of the invention, there is provided a steerable catheter having two electrodes for making bipolar measurements. As shown in FIGs. 1 and 2, catheter **10** comprises an elongated catheter body **12** having proximal and distal ends, a tip section **14** at the distal end of the catheter body **12**, and a control handle **16** at the proximal end of the catheter body **12**.

[0020] With reference to FIG. 2, the catheter body **12** comprises an elongated tubular construction having a single, axial or central lumen **18**. The catheter body **12** is flexible, i.e., bendable, but substantially non-compressible along its length. The catheter body **12** can be of any suitable construction and made of any suitable material. A presently preferred construction comprises an outer wall **22** made of a polyurethane, or PEBAX. The outer wall **22** comprises an imbedded braided mesh of high-strength steel, stainless steel or the like to increase torsional stiffness of the catheter body **12** so that, when the control handle **16** is rotated, the tip section **14** of the catheter **10** will rotate in a corresponding manner.

[0021] The outer diameter of the catheter body **12** is not critical, but is preferably no more than about 8 french, more preferably about 7 french. Likewise the thickness of the outer wall **22** is not critical, but is thin enough so that the central lumen **18** can accommodate a puller wire, lead wires, and any other wires, cables or tubes. The inner surface of the outer wall **22** is lined with a stiffening tube **20**, which can be made of any suitable material, such as polyimide or nylon. The stiffening tube **20**, along with the braided outer wall **22**, provides improved torsional stability while at the same time minimizing the wall thickness of the catheter, thus maximizing the diameter of the central lumen **18**. The outer diameter of the stiffening tube **20** is about the same as or slightly smaller than the inner diameter of the outer wall **22**. Polyimide tubing is presently preferred for the stiffening tube **20** because it may be very thin walled while still providing very good stiffness. This maximizes the diameter of the central lumen **18** without sacrificing strength and stiffness.

[0022] One preferred catheter has an outer wall **22** with an outer diameter of from about 0.090 inch to about 0.098 inch and an inner diameter of from about 0.061 inch to about 0.065 inch and a polyimide stiffening tube **20** having an outer diameter of from about 0.060 inch to about 0.064 inch and an inner diameter of from about 0.051 inch to about 0.056 inch. As would be recognized

by one skilled in the art, the catheter body construction can be modified as desired. For example, the stiffening tube can be eliminated.

[0023] As shown in FIGs. 3A, 3B, 4 and 5, the tip section **14** comprises a short section of tubing **19** having three lumens **30**, **32** and **34**. The tubing **19** is made of a suitable non-toxic material that is preferably more flexible than the catheter body **12**. A presently preferred material for the tubing **19** is braided polyurethane, i.e., polyurethane with an embedded mesh of braided high-strength steel, stainless steel or the like. The outer diameter of the tip section **14**, like that of the catheter body **12**, is preferably no greater than about 8 french, more preferably about 7 french. The size of the lumens is not critical and can vary depending on the specific application. In a particularly preferred embodiment, the tip section **14** has an outer diameter of about 7 french (.092 inch) and the first lumen **30** and second lumen **32** are generally about the same size, each having a diameter of from about 0.020 inch to about 0.024 inch, preferably 0.022 inch, with the third lumen **34** having a slightly larger diameter of from about 0.032 inch to about 0.038 inch, preferably 0.036 inch.

[0024] A preferred means for attaching the catheter body **12** to the tip section **14** is illustrated in FIG. 2. The proximal end of the tip section **14** comprises an outer circumferential notch **24** that receives the inner surface of the outer wall **22** of the catheter body **12**. The tip section **14** and catheter body **12** are attached by adhesive (e.g., polyurethane glue) or the like. Before the tip section **14** and catheter body **12** are attached, however, the stiffening tube **20** is inserted into the catheter body **12**. The distal end of the stiffening tube **20** is fixedly attached near the distal end of the catheter body **12** by forming a glue joint (not shown) with polyurethane glue or the like. Preferably a small distance, e.g., about 3 mm, is provided between the distal end of the catheter body **12** and the distal end of the stiffening tube **20** to permit room for the catheter body **12** to receive the notch **24** of the tip section **14**. A force is applied to the proximal end of the stiffening tube **20**, and, while the stiffening tube **20** is under compression, a first glue joint (not shown) is made between the stiffening tube **20** and the outer wall **22** by a fast drying glue, e.g. Super Glue®. Thereafter a second glue joint (not shown) is formed between the proximal ends of the stiffening tube **20** and outer wall **22** using a slower drying but stronger glue, e.g., polyurethane.

[0025] At the distal end of the tip section **14** is a tip electrode **36**. Preferably the tip electrode **36** has a diameter about the same as the outer diameter of the tubing **19**. The tip electrode **36** can be made from any suitable material, such as platinum, gold, or stainless steel, and is preferably machined from platinum-iridium rod (90% platinum/10% iridium).

[0026] The tip electrode **36** has a total length preferably ranging from about 4 mm to about 14 mm, more preferably from about 6 mm to about 12 mm. As depicted in FIGs. 3A, 3B and 5, the tip electrode **36** comprises

an exposed region **35** at its distal end, a stem **37** at its proximal end, and a central region **38** interposed the exposed region **35** and the stem **37**. The exposed region **35** has a length preferably ranging from about 1.5 mm to about 4.0 mm, more preferably from about 2.0 mm to about 3.0 mm, still more preferably from about 2.3 mm to about 2.5 mm, and an outer diameter preferably ranging from about 2.0 mm to about 3.0 mm, more preferably from about 2.3 mm to about 2.5 mm.

[0027] In a particularly preferred arrangement, the exposed region has a length similar to its diameter. Preferably the ratio of the length to the diameter ranges from about 0.8:1 to about 1.2:1, more preferably from about 0.9:1 to about 1.1:1. In a particularly preferred embodiment, the length of the exposed region is approximately equal to the diameter of the exposed region. Thus, for example, for a 7 French electrode catheter, the tip electrode preferably has a length and diameter equal to about 2.3 mm. With such a design, the surface area of the tip electrode (having a generally hemispherical distal end) is the same in the parallel orientation and in the perpendicular orientation. These uniform dimensions provide a generally constant contact area between the exposed region **35** of the tip electrode **36** and the heart tissue, irrespective of the orientation of the tip section **14** relative to the heart tissue. As a result, more predictable lesion sizes can be achieved.

[0028] The central region **38** has a length preferably ranging from about 2 mm to about 10 mm, more preferably from about 3 mm to about 8 mm, still more preferably from about 3.5 mm to about 6 mm. In the depicted embodiment, the outer diameter of the central region **38** is slightly less than the outer diameter of the exposed region **35**, and is preferably from about 0.1 mm to about 0.3 mm less than the outer diameter of the exposed region. As described in more detail below, the central region **38** is provided with a covering and a ring electrode is mounted thereon. When the outer diameter of the central region **38** is slightly less than the outer diameter of the exposed region **35**, the outer diameter of the ring electrode mounted thereon will generally correspond to the outer diameter of the exposed region. Alternatively, the outer diameter of the ring electrode (and optionally the outer diameter of the central region **38**) can be greater than the outer diameter of the exposed region **35**.

[0029] The stem **37** is provided for mounting of the tip electrode **36** onto the tubing **19** of the tip section **14**. The stem has a length preferably ranging from about 1 mm to about 4 mm, more preferably from about 1.5 mm to about 2.5 mm, still more preferably about 2.0 mm. The outer diameter of the stem **37** is less than the outer diameter of the central region **38**, and preferably ranging from about 1.5 mm to about 2.0. The dimensions of the stem **37** are not critical, so long as the stem can fit within the distal end of the tubing **19**. A hole is drilled into the distal end of the tubing **19**, and the proximal end of the stem **37** is glued into the hole, with polyurethane glue

or the like. Preferably the proximal end of the stem **37** does not contact the inside of the tubing **19** so that a slot **26** is provided therebetween, to assist in the anchoring of a puller wire discussed in more detail below.

5 **[0030]** Alternatively, the stem **37** can be eliminated, and the proximal end of the tip electrode **36** can be mounted onto the tubing **19** by any other suitable means known in the art. For example, the distal end of the tubing **19** can be inserted into an opening in this proximal end of the tip electrode **36**, e.g., within the central region **38**, and fixed in place with glue or the like.

[0031] The stem **37**, central region **38**, and exposed region **35** are generally solid with a blind hole **31** extending from the proximal end of the stem **37** part way into the exposed region **35**. The blind hole **31** comprises a proximal section **31a** having a first diameter and a distal section **31b** having a second diameter less than the first diameter. The proximal section **31a** has a length preferably ranging from about 5.5 mm to 6.0 mm, more preferably about 5.7 mm, and a diameter preferably ranging from about 1.0 mm to 1.5 mm, more preferably about 1.3 mm. The distal section **31b** preferably begins at the proximal end of the exposed region **35** and extends into the exposed region **35** a distance such that the distal end of the hole does not extend out through the distal end of the exposed region, but is preferably within about 0.5 mm of the distal end of the exposed region. The diameter of the distal section **31b** preferably ranges from about 0.3 mm to 0.7 mm, more preferably about 0.5 mm.

10 **20** **25** **30** **35** Preferably the distal section **31b** is designed so that a thermocouple or the like mounted therein, as discussed in more detail below, is generally in the center of the exposed region **35**.

[0032] The central region **38** of the tip electrode **36** is provided with an electrically insulating and thermally conductive layer **55** over at least a portion, and preferably over all, of the outer surface of the central region **38**. The electrically insulating and thermally conductive layer **55** is made of any suitable electrically insulating and thermally conductive material, including, but not limited to diamond, carbon, parylene, polyimide, polyester, polyurethane, epoxy, ceramic, and combinations thereof. The electrically insulating and thermally conductive layer **55** preferably has a thickness no greater than about 10 μ m, more preferably ranging from about 0.5 μ m to about 10 μ m, still more preferably from about 1 μ m to about 5 μ m.

40 **45** **50** **55** **[0033]** The insulating layer **55** can be applied by any suitable technique. For example, a layer of parylene can be applied by a deposition coating technique where the exposed region **35** of the tip electrode **36** is placed in a deposition chamber. The chamber functions to both hold the tip electrode **36** in place, as well as protect the exposed region **35** from exposure to parylene deposits. Alternatively, the insulating layer **55** may comprise a shrink-sleeve made of, for example, a thin polyester (e.g., about 0.00025 inch), or may comprise a thin coating of polyurethane or the like painted onto the surface of

the central region **38**.

[0034] A ring electrode **39** is mounted on the central portion **38** of the tip electrode **36**. The ring electrode **39** is slid over the electrically insulating layer **55** and fixed in place by glue or the like. The electrically insulating layer **55** insulates the tip electrode **36** from the ring electrode **39**. The ring electrode **39** can be made of any suitable electrically-conductive material, such as platinum, gold, or stainless steel, and is preferably made from a platinum-iridium alloy (90% platinum/10% iridium). In the depicted embodiment, the ring electrode **39** is mounted near the distal end of the central portion **38** in close proximity to the exposed region **35**. In this embodiment, the ring electrode **39** (i.e., the distal edge of the ring electrode) is preferably spaced apart from the exposed region **35** a distance no greater than about 2 mm, more preferably from about 0.2 mm to about 1.5 mm, more preferably from about 0.2 mm to about 0.5 mm. Alternatively, the ring electrode **39** can be positioned closer to the flexible tubing **19**, in which case the ring electrode (i.e., the proximal edge of the ring electrode) is preferably spaced apart from the distal end of the tubing a distance no greater than about 2 mm. The ring electrode **39** has a width preferably ranging from about 0.4 mm to about 2.0 mm, more preferably from about 0.5 mm to about 1.5 mm, still more preferably from about 0.6 mm to about 1.0 mm. Preferably the outer diameter of the ring electrode **39** is the same as the outer diameter of the exposed region **35** of the tip electrode **36**.

[0035] The tip electrode **36** and ring electrode **39** are each connected to a separate lead wire **44**. The lead wires **44** extend through the first lumen **30** of tip section **14**, the central lumen **18** of the catheter body **12**, and the control handle **16**, and terminate at their proximal end in an input jack (not shown) that may be plugged into an appropriate signal processing unit (not shown) and source of RF energy (not shown). The portion of the lead wires **44** extending through the central lumen **18** of the catheter body **12**, control handle **16** and proximal end of the tip section **14** may be enclosed within a protective sheath **49**, which can be made of any suitable material, preferably polyimide. The protective sheath **49** is preferably anchored at its distal end to the proximal end of the tip section **14** by gluing it in the first lumen **30** with polyurethane glue or the like.

[0036] The lead wires **44** are attached to the tip electrode **36** and ring electrodes **39** by any conventional technique. Connection of a lead wire **44** to the tip electrode **36** is accomplished, for example, by soldering the lead wire **44** into a first hole **47** located along the stem **37** of the tip electrode **36**, as shown in FIG. 3B.

[0037] Connection of a lead wire **44** to the ring electrode **39** is preferably accomplished by first making a second hole **48** through the central region **38** of the tip electrode **36** and through the insulating layer **55**. A lead wire **44** is then drawn through the hole **48**. The ends of the lead wire **44** are then stripped of any coating and soldered or welded to the underside of the ring electrode

39, which is then slid into position over the hole **48** and fixed in place with polyurethane glue or the like.

[0038] Two additional ring electrodes **59** are mounted of the distal end the tip section **14**. The ring electrodes **59** are slid over the flexible tubing **19** and fixed in place by glue or the like. The position and spacing of the additional ring electrode **59** are not critical. If desired, additional ring electrodes **59** may be used and can be positioned over the flexible tubing **19** of the tip section **14** in a similar manner.

[0039] A temperature sensing means is provided for the tip electrode **36** and, if desired, the ring electrodes **39** and/or **59**. Any conventional temperature sensing means, e.g., a thermocouple or thermistor, may be

15 used. A preferred temperature sensing means for the tip electrode **36** comprises a thermocouple formed by an enameled wire pair. One wire of the wire pair is a copper wire **41**, e.g., a number **40** copper wire. The other wire of the wire pair is a constantan wire **45**. The wires

20 **41** and **45** of the wire pair are electrically isolated from each other except at their distal ends where they are twisted together, covered with a short piece of plastic tubing **58**, e.g., polyamide, and covered with epoxy (as shown in FIG. 3c). The plastic tubing **58** is then attached

25 in the distal section **31b** of the blind hole **31** in the tip electrode **36**, by polyurethane glue or the like. Alternatively, the wires **41** and **45** can be soldered into the distal section **31b**.

[0040] The wires **41** and **45** extend through the second lumen **32** in the tip section **14** and through the central lumen **18** of the catheter body **12**. Within the second lumen **32** and central lumen **18**, the wires **41** and **45** extend through the protective sheath **49** with the lead wires **44**. The wires **41** and **45** then extend out through the control handle **16** and to a connector (not shown) connectable to a temperature monitor (not shown).

[0041] Alternatively, the temperature sensing means may be a thermistor. A suitable thermistor for use in the present invention is Model No. AB6N2-GC 14KA 143E/40 37C sold by Thermometrics (New Jersey).

[0042] Additionally, a mechanism is provided for deflecting the tip section **14**. In one embodiment, the mechanism comprises a puller wire **50** extending through the catheter body **12**. The puller wire **50** is anchored at its proximal end to the control handle **16** and is anchored at its distal end to the tip section **14**. The puller wire **50** is made of any suitable metal, such as stainless steel or Nitinol, and is preferably coated with Teflon® or the like. The coating imparts lubricity to the puller wire **50**. The puller wire **50** preferably has a diameter ranging from about 0.006 to about 0.010 inch.

[0043] A compression coil **52** is situated within the catheter body **12** in surrounding relation to the puller wire **50**. The compression coil **52** extends from the proximal end of the catheter body **12** to the proximal end of the tip section **14**. The compression coil **52** is made of any suitable metal, preferably stainless steel. The compression coil **52** is tightly wound on itself to provide flex-

ability, i.e., bending, but to resist compression. The inner diameter of the compression coil 52 is preferably slightly larger than the diameter of the puller wire 50. The Teflon® coating on the puller wire 50 allows it to slide freely within the compression coil 52. If desired, particularly if the lead wires 44 are not enclosed by a protective sheath 49, the outer surface of the compression coil 52 can be covered by a flexible, non-conductive sheath 46, e.g., made of polyimide tubing, to prevent contact between the compression coil 52 and any other wires within in the catheter body 12.

[0044] The compression coil 52 is anchored at its proximal end to the proximal end of the stiffening tube 20 in the catheter body 12 by glue joint 51 and at its distal end to the tip section 14 by glue joint 53. Both glue joints 51 and 53 preferably comprise polyurethane glue or the like. The glue may be applied by means of a syringe or the like through a hole made between the outer surface of the catheter body 12 and the central lumen 18. Such a hole may be formed, for example, by a needle or the like that punctures the outer wall 22 of the catheter body 12 and the stiffening tube 20 which is heated sufficiently to form a permanent hole. The glue is then introduced through the hole to the outer surface of the compression coil 52 and wicks around the outer circumference to form a glue joint about the entire circumference of the compression coil 52.

[0045] The puller wire 50 extends into the second lumen 32 of the tip section 14. The puller wire 50 is anchored at its distal end to the distal end of the tip section 14 by an anchor 54. A preferred method for anchoring the puller wire 50 within the slot 26 is by soldering or welding the distal end of the puller wire 50 to an anchor 54, preferably formed from a small section of stainless steel ribbon or the like. The anchor 54 is displaced inside the slot 26 between the inside of the tubing 19 and the proximal end of the stem 37 in a transverse arrangement to the puller wire, forming a T-bar or anchor. Because the length of the anchor 54 is longer than the diameter of the second lumen 32, the anchor 54 cannot be pulled thought the lumen 32. Alternatively, the puller wire 50 can be anchored in a blind hole in the tip electrode 36, as described, for example, in U.S. Patent No. 6,027,473, the disclosure of which is incorporated herein by reference. In another alternative, the puller wire 42 can be anchored to the side of the tip section 14, as described, for example, in EP-A-0 904 796,

the disclosure of which is incorporated herein by reference. Within the second lumen 32 of the tip section 14, the puller wire 50 extends through a plastic, preferably Teflon®, sheath 56, which prevents the puller wire 50 from cutting into the wall of the tubing 19 when the tip section is deflected.

[0046] A safety wire 57 extends through the catheter body 12 and is anchored at its distal end to the tip electrode 36. The safety wire 57 is preferably a Monell wire wrapped with copper. The safety wire 57 is anchored to the tip electrode 36, for example, by soldering the safety

wire 57 into the first hole 47 in the stem 37. At its proximal end, the safety wire 57 is wrapped around the compression coil 52 at a location within the catheter body 12.

[0047] An electromagnetic location sensor 72 is contained within the tip electrode 36. The electromagnetic sensor 72 is located within proximal section 31a of the blind hole 31 in the tip electrode 36 and fixed by polyurethane glue or the like. Depending on the dimensions of the tip electrode 36 and sensor 72, it may be desirable for the sensor to extend, at least in part, into the stem 37 of the tip electrode and possibly even into the distal end of the tubing 19 of the tip section. The electromagnetic sensor 72 is connected to an electromagnetic sensor cable 74, which extends through the third lumen 34 of the tip section 14, through the catheter body 12, and out through control handle 16. The electromagnetic sensor cable 74 comprises multiple wires encased within a plastic covered sheath. In the control handle 16, the sensor cable 74 is connected to a circuit board (not shown).

[0048] The circuit board amplifies the signal received from the electromagnetic sensor 72 and transmits it to a computer in a form understandable by the computer. Also, because the catheter is designed for single use only, the circuit board contains an EPROM chip which shuts down the circuit board after the catheter has been used. This prevents the catheter, or at least the electromagnetic sensor, from being used twice. Suitable electromagnetic sensors for use with the present invention are described, for example, in EP-A-0 989 384 and U.S. Patent Nos. 5,558,091, 5,443,489, 5,480,422, 5,546,951, 5,568,809, and 5,391,199, the disclosures of which are incorporated herein by reference.

[0049] If desired, the catheter can be multidirectional, i.e., having two or more puller wires to enhance the ability to manipulate the tip section in more than one direction or to form two or more different curves. A description of such a design is provided in EP-A-0 904 796, EP-A-0 985 423, EP-A-0 982 407, EP-A-1 005 839 and EP-A-1 038 545, the disclosures of which is incorporated herein by reference.

[0050] The catheters in accordance with the present invention are particularly suitable for mapping the heart and ablating heart tissue, such as accessory signal pathways causing arrhythmias. In operation, the distal end of the catheter 10 is inserted into a vein or artery and advanced into the heart. To assist in positioning the tip section 14 of the catheter 10 at a desired position within the heart, the puller wire 50 and control handle 16 are used to deflect the tip section 14. Once the tip section 14 has been positioned at or near the desired location of the heart tissue, the electrical activity of the

heart may be identified, evaluated or mapped, and electrophysiological sources of arrhythmia may be identified and/or treated.

[0051] More specifically the bipolar electrode pair, namely, the exposed region 35 of the tip electrode 36 and ring electrode 39 mounted on the tip electrode, is used to map the electrical activity of the heart. The close proximity of the ring electrode 39 to the exposed region 35 of the tip electrode 36 provides the catheter with more accurate bipolar mapping capabilities. Because of their close proximity, the electrodes 36 and 39 are exposed to nearly identical noise and far-field background signals. A bipolar electrogram displays the difference of the two signals, so essentially only the electrical activity from the nearby tissue is recorded. Closely spaced electrodes provide more discrete electrograms.

[0052] Additionally, the electrically insulating layer 55 limits the electrically active surface area of the tip electrode 36 to the exposed region 35, providing improved electrogram resolution compared to a conventional tip electrode. More specifically, electrograms recorded from the relatively small exposed region 35 will be more discrete, reporting electrical activity from a smaller area of tissue.

[0053] The electromagnetic location sensor 72 in the tip section 14 of the catheter is used to provide a map of the heart so that the physician can better determine where to ablate and can have a better sense for where the tip section 14 is located during the procedure. In use, the patient is placed in a magnetic field generated, for example, by situating under the patient a pad containing coils for generating a magnetic field, and a reference electromagnetic sensor is fixed relative to the patient, e.g., taped to the patient's back. Signals generated in the heart by both the fixed reference sensor and the electromagnetic location sensor 72 in the catheter are amplified and transmitted to a computer that analyzes the signals and displays them on a monitor. By this method, the precise location of the location sensor 72 (and thus the tip section 14, including the tip electrode 36) relative to the reference sensor can be ascertained and visually displayed. The sensor 72 can also detect displacement of the catheter that is caused by contraction of the heart muscle.

[0054] The electromagnetic mapping sensor 72 preferably is used in combination with the tip electrode 36 and ring electrode 39. By combining the electromagnetic sensor 72 and electrodes 36 and 39, a physician can simultaneously map the contours or shape of the heart chamber, the electrical activity of the heart, and the extent of displacement of the catheter. The tip electrode 36 and ring electrode 38 are used to monitor the strength of the electrical signals at a particular location. As would be recognized by one skilled in the art, the inventive tip electrode design can be effectively used without the inclusion of a location sensor, and thus the electromagnetic sensor 72 can be eliminated if desired.

[0055] Once the electrical activity of the heart is de-

termined and mapped, if desired, the physician uses the same catheter for ablating the heart tissue. The relatively large surface area of the tip electrode 36, which includes the exposed region 35 as well as the central region 38 covered with the thermally conductive layer 55,

5 enhances the ability of the electrode to dissipate heat during ablation compared to a comparable tip electrode having a length closer to the that of the exposed region 35 of the present catheter. Compared to a standard 4 mm tip electrode, the tip electrode of the present invention having a preferred length (outside of the plastic tubing 19) of about 6 mm to about 8 mm provides improved convective cooling by the passing blood, such that additional power can be applied to the tissue. However, 10 conventional 8 mm tip electrodes require more power than the inventive tip electrode. The tip electrode of the present invention preferably has an exposed length of only about 2 mm to about 3 mm, reducing the amount of power required to ablate compared to a tip electrode 15 have an exposed length of 8 mm. Further, a conventional 8 mm tip electrode uses more energy heating the surrounding blood rather than heating the adjacent heart tissue. This heating of the blood can cause significant coagulation of the blood along the surface of the tip electrode. 20 The present invention overcomes this problem by providing an electrically insulating, but thermally conductive layer over the non-exposed portion of the tip electrode 36, allowing the electrical power to be concentrated at the exposed region 35, while the insulated portion (the central region 38) of the tip electrode is convectively cooled by passing blood.

[0056] As a result of this design, more power can be applied to the tissue with the inventive electrode compared to a standard tip electrode having a total length 25 equal to the length of the exposed region 35 of the inventive electrode. This holds true because the blood can more efficiently cool the inventive electrode compared to the standard tip electrode. Additionally, the inventive electrode can create the same sized lesion as a standard tip electrode having a total length equal to the total length of the inventive electrode (but without an electrically insulating and thermally conductive covering), but using less power. This holds true because the inventive electrode has a higher current density than a standard 30 tip electrode, while still having similar cooling capabilities, and therefore less power is needed.

[0057] Additionally, as discussed above, electrode impedance is routinely monitored during ablation to detect the potential formation of dangerous char or thrombus on the tip electrode. Because the electrically active area (i.e., the exposed region 35) of the inventive tip electrode is smaller than with conventional ablation tip electrodes that offer similar cooling ability, changes in impedance due to char or thrombus formation are more 35 readily detected with the inventive catheter.

[0058] The preceding description has been presented with reference to presently preferred embodiments of the invention. Workers skilled in the art and technology

to which this invention pertains will appreciate that alterations and changes in the described structure may be practiced without meaningfully departing from the principal, spirit and scope of this invention.

[0059] Accordingly, the foregoing description should not be read as pertaining only to the precise structures described and illustrated in the accompanying drawings, but rather should be read consistent with and as support to the following claims which are to have their fullest and fair scope.

Claims

1. A catheter comprising:

an elongated flexible body having a distal region and at least one lumen extending therethrough;

a tip electrode mounted on the distal region, the tip electrode having an exposed distal region having proximal and distal ends and an isolated region proximal to the exposed distal region, wherein the isolated region has an outer surface provided with an electrically insulating and thermally conductive layer; and

a second electrode mounted on the isolated region on the tip electrode.

2. A catheter as claimed in claim 1, wherein the second electrode is a ring electrode.

3. A catheter as claimed in claim 1 or claim 2, wherein the total length of the exposed distal region and the isolated region ranges from 4 mm to 12 mm, preferably from 6 mm to 10 mm.

4. A catheter as claimed in any one of claims 1 to 3, wherein the exposed distal region has a length ranging from 1.5 mm to 4.0 mm, preferably from 2 mm to 3 mm.

5. A catheter as claimed in any one of claims 1 to 4, wherein the second electrode is mounted a distance from the proximal end of the exposed region no more than about 2mm.

6. A catheter as claimed in any one of claims 1 to 5, wherein the second electrode is mounted a distance from the distal end of the catheter body no more than about 2 mm.

7. A catheter as claimed in any one of claims 1 to 6, wherein the electrically insulating and thermally conductive layer comprises a composition selected from the group consisting of diamond, carbon, parylene, polyimide, polyester, polyurethane, epoxy, ceramic, and combinations thereof.

8. A catheter as claimed in any one of claims 1 to 7, wherein the electrically insulating and thermally conductive layer has a thickness no greater than about 10 μm , preferably ranging from 1 μm to 5 μm .

9. A catheter as claimed in any one of claims 1 to 8, wherein the isolated region has an outer diameter less than the outer diameter of the exposed region.

10. A catheter as claimed in any one of claims 1 to 9, wherein the exposed region has a length approximately equal to its outer diameter.

15

20

25

30

35

40

45

50

55

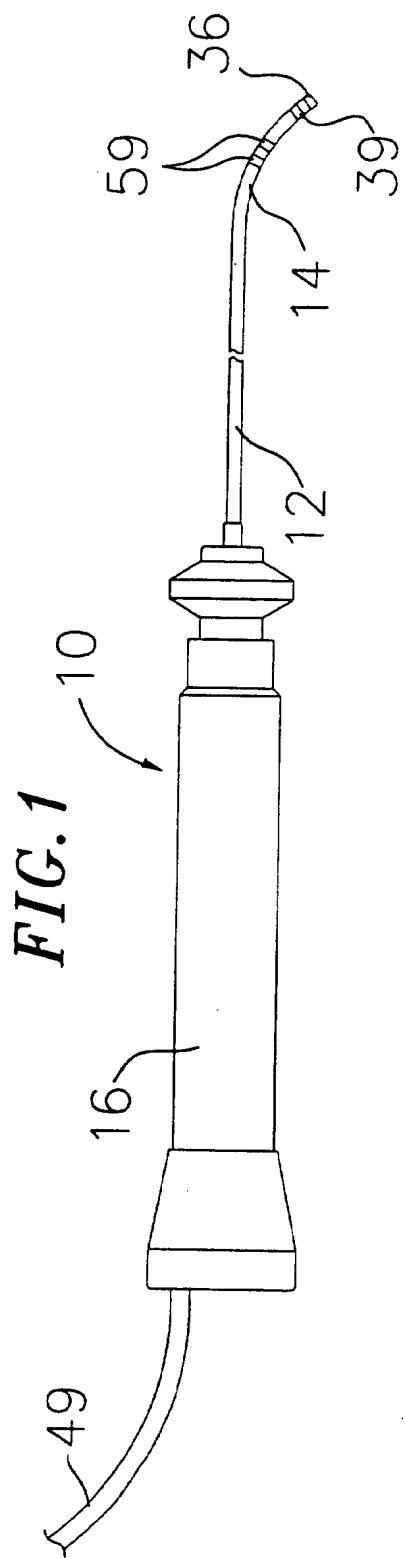


FIG. 2

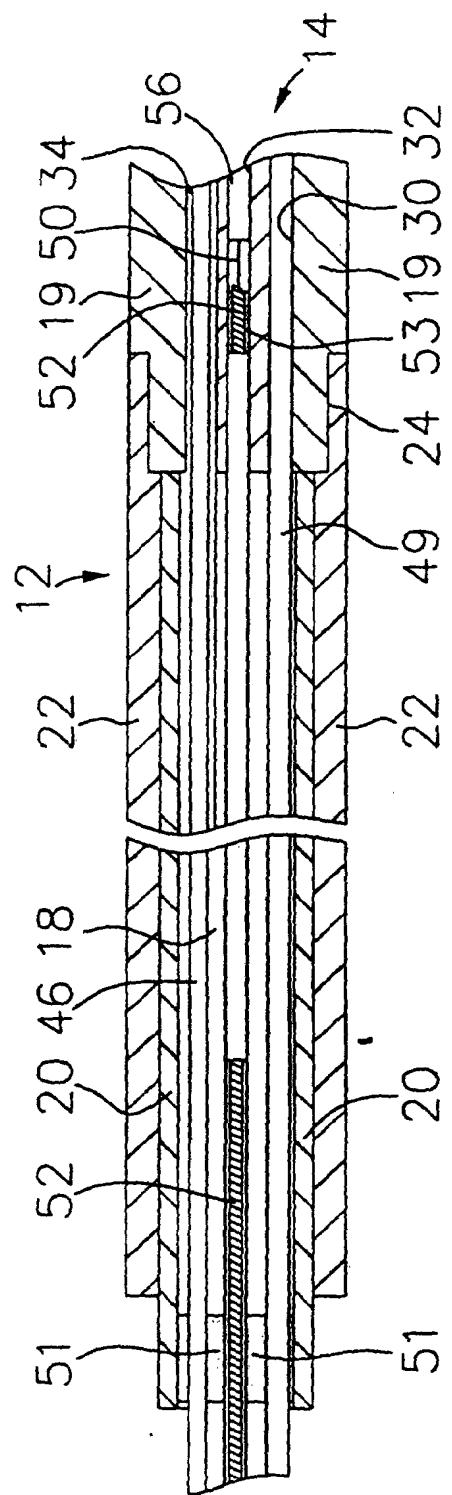


FIG. 3A

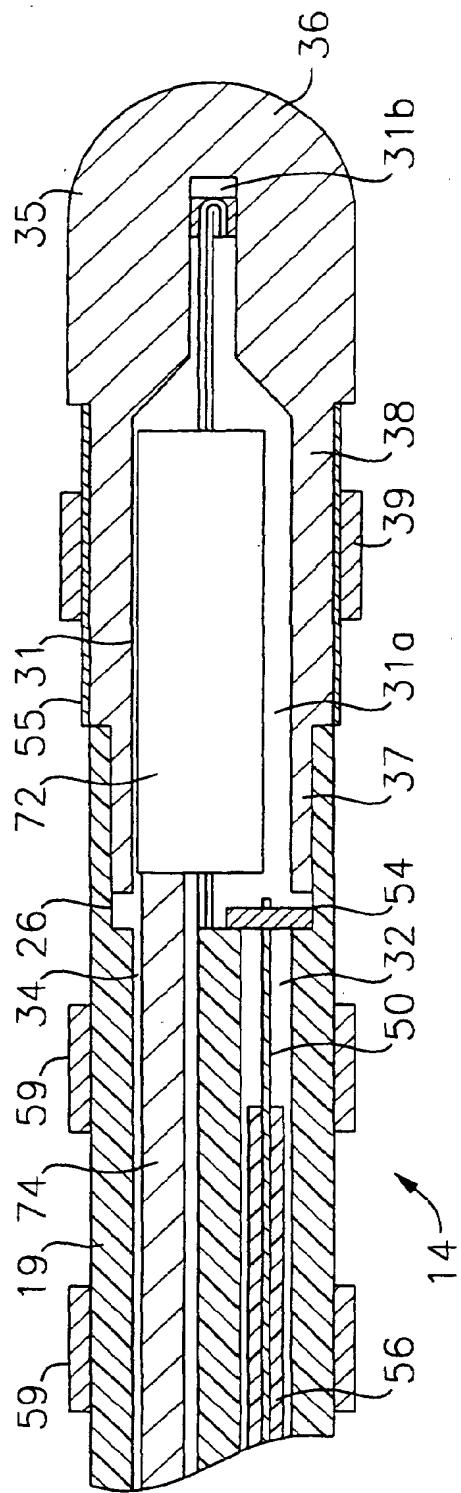
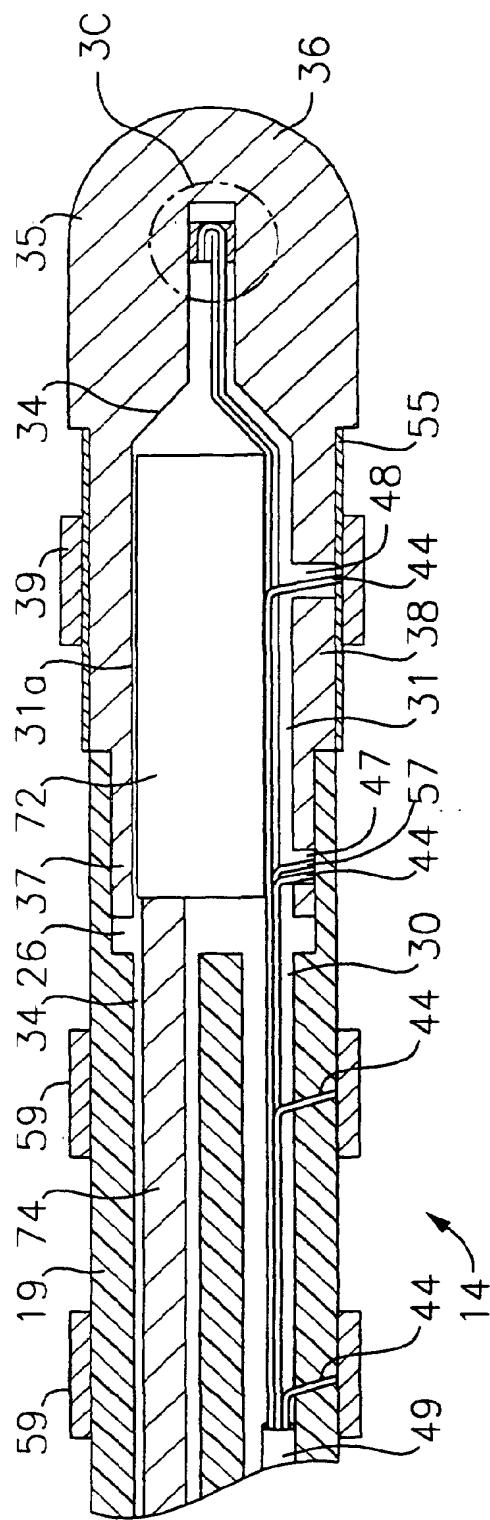


FIG. 3B



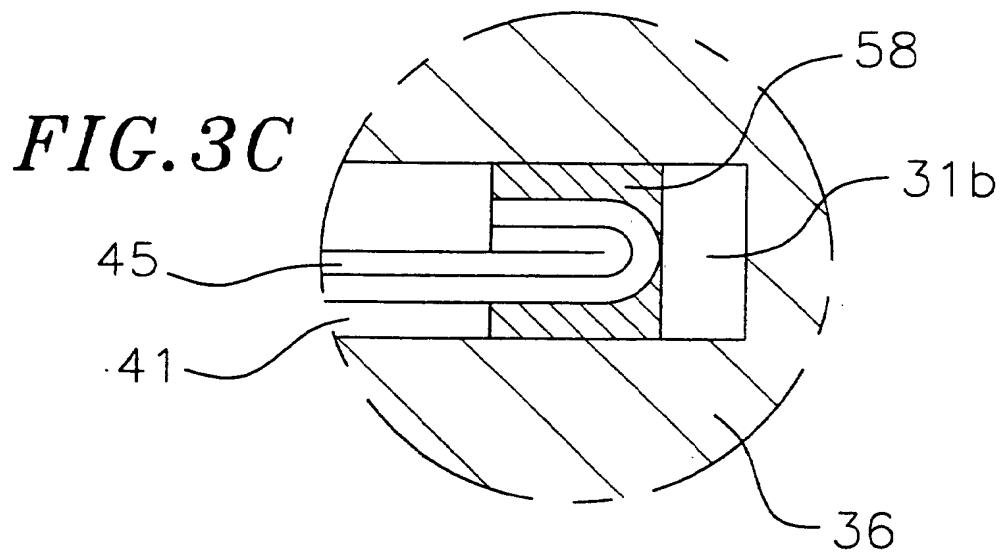
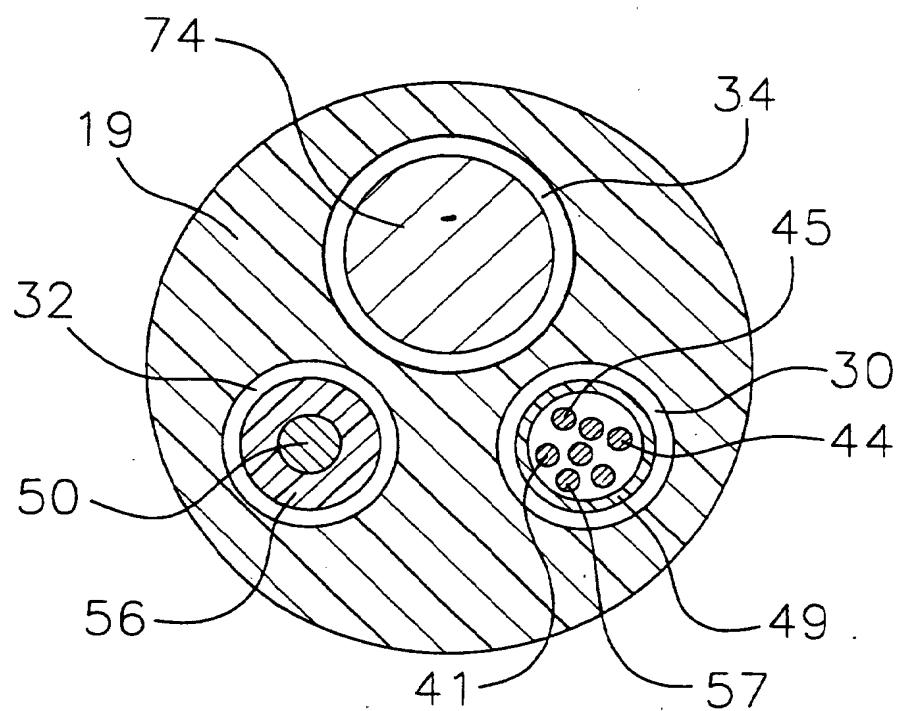


FIG. 4





European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 01 30 5844

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
A	US 5 545 161 A (IMRAN MIR A) 13 August 1996 (1996-08-13) -----		A61B18/14
A	US 5 257 635 A (LANGBERG EDWIN) 2 November 1993 (1993-11-02) -----		
			TECHNICAL FIELDS SEARCHED (Int.Cl.7)
			A61B
<p>The present search report has been drawn up for all claims</p>			
Place of search	Date of completion of the search	Examiner	
THE HAGUE	25 September 2001	Papone, F	
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document			
T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.

EP 01 30 5844

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on. The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

25-09-2001

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
US 5545161	A	13-08-1996		US 5697927 A US 5348554 A AU 673015 B2 AU 5201993 A CA 2110309 A1 EP 0608609 A2 JP 2562861 B2 JP 6254103 A US 5423811 A US 5658278 A	16-12-1997 20-09-1994 24-10-1996 16-06-1994 02-06-1994 03-08-1994 11-12-1996 13-09-1994 13-06-1995 19-08-1997
US 5257635	A	02-11-1993		US 4945912 A AT 150274 T AU 4187893 A AU 645486 B2 AU 4660189 A CA 2003689 A1 DE 68927892 D1 EP 0445223 A1 EP 0745354 A2 WO 9006079 A1 US 5370644 A US 5246438 A US 5230349 A CA 2070403 A1 EP 0497959 A1 WO 9202272 A1	07-08-1990 15-04-1997 23-09-1993 20-01-1994 26-06-1990 25-05-1990 24-04-1997 11-09-1991 04-12-1996 14-06-1990 06-12-1994 21-09-1993 27-07-1993 04-02-1992 12-08-1992 20-02-1992